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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,555

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Nobuo Shimamoto

TSU-008

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38051

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08/17/2009

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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,555	Applicant(s) SHIMAMOTO ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,9 and 13-27 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,9 and 13-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/02/08&3/26/07</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The preliminary amendment filed 9/2/06 has been entered. Claims 1-6, 8-9, and 13-26 are pending.

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 18-26 have been renumbered as 19-27.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 4 is vague and indefinite because of the phrase “no frequency”. It is unclear what is meant regarding the phrase.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 8, 13 and 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Singer et al. (Nucleic Acid Research, 1997, Vol. 25(4), pg. 781-786).

Singer et al. disclose construction of a genomic library in which denatured genomic DNA is primed with primers having random nine nucleotides at the 3' end. This step is interpreted as a first step and then the library is amplified by PCR using primers of completely fixed sequences, one of which adds a T7 promoter (primer A) (see pg. 782, fig. 1 and column 1, first paragraph). The genomic DNA is from human placenta; *E. coli* B and *S. cerevisiae* (see pg. 781, column 2, and last paragraph). The primer is designed to have a fixed sequence at the 5' end and nine random nucleotides at the 3' end (see pg. 783, column 2, forth paragraph). Singer et al. also indicated that a set of sub-fragments is generated by one genome-specific primer (see pg. 783, fig. 2).

Since the phrases "frequently appearing", and "no or low frequency" are not clearly defined in the specification, the teachings of Singer et al. anticipate the limitations of the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5-6, 9, 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al. (Nucleic Acid Research, 1997, Vol. 25(4), pg. 781-786) as applied to claim 1-4 and 21-27 above, and further in view of Lao et al. (WO 03/097794, issued Nov. 27, 2003).

The teachings of Singer et al. are set forth in section 5 above. Singer et al. do not disclose the limitations of claims 5-6, 9 and 14-20.

Lao et al. disclose a method of amplifying target DNA (see pg. 1 [0005]). The target DNA is genomic DNA which is used as a template (see pg. 6, [0026]). The primer is designed to have a 3' specific region which is about 4-12 bases in length. The 3' specific region is designed to bind to a genomic sequence occurring in the human genome with a frequency of about 0.01% and 2.00%. The 3' specific region is able to anneal to specified sites in the genome. The length of the specific region can be between about 5 and 6 bases (see pg. 7, [0031]). An annealing temperature is 45⁰C for 3 min. and 72⁰C for 1 min (see pg. 18, [0081]).

Lao et al. do not explicitly disclose a 6mer sequence selected from the 1st to 20th frequently appearing sequences among all the known 6mer sequences.

Lao et al. disclose that the specific region is designed to specifically bind short sequences occurring with high frequency in the genome to be amplified (see pg. 12, [0064]) in which the benefits of using 9-base length and 5-base length in the specific region of the primer are discussed. The conclusion is that primers with specific regions less than 9 bases are

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contemplated and the specific region of between about 5 and 6 bases is also contemplated (see pg. 12, [0064]). The top 50 most frequent 5-mers are listed in table 1.

Since the region is specific, it inherently teaches that these 5- or 6- base sequences are known.

One of ordinary skill would have been motivated to prepare a genome library with a primer designed to have a 3'-terminal, a 6mer sequence selected from the 1st to 20th most frequently appearing sequences among all known 6mer sequences with a reasonable expectations of success because of the discussion of Lao et al. It would have been prima facie obvious to design a primer with a 3'-terminal, a 6mer sequence selected from the 1st to 20th most frequently appearing sequences among all known 6mer sequences.

In addition, one of ordinary skill in the art would have been motivated to apply the conditions for PCR cycles as taught by Lao et al. (see pg. 18, [0081]) because by doing so the efficiency of amplification is increased (see pg. 19, [0085]-[0086]). It would have been prima facie obvious to apply the conditions for PCR as recited in the instant claims.

Summary

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

/Joyce Tung/
Examiner, Art Unit 1637
July 31, 2009